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| 10/523,794 | 02/09/2005 | Thomas Heidenfelder | 264508US0PCT | 6162 |

22850 7590 01/30/2008
OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C.
1940 DUKE STREET
ALEXANDRIA, VA 22314

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| EXAMINER |
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BROWN, COURTNEY A

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| ART UNIT | PAPER NUMBER |
|----------|--------------|

1616

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| NOTIFICATION DATE | DELIVERY MODE |
|-------------------|---------------|

01/30/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/523,794

Applicant(s)

HEIDENFELDER ET AL.

Examiner

Courtney A. Brown

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is /are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
- Paper No(s)/Mail Date 2/09/2005.

- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____.

DETAILED ACTION

Priority

Priority to German Foreign Application 102-38-144.5 filed on August 15, 2002 is acknowledged.

Information Disclosure Statement

Receipt of Information Disclosure Statements filed on February 9, 2005 is acknowledged.

Status of the Claims

Applicant's claims are drawn toward the use of diketopiperazine derivatives as photostable uv-filters in cosmetic and pharmaceutical preparations. Claims 1- 16 filed on February 5, 2005 are currently pending examination for patentability.

Claim Objections

Claims 7 and 12 are objected to because they fail to further limit previous claims 4 and 1.

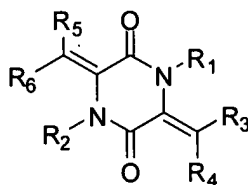
Claim Rejections- 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 7-11, and 14-16 are rejected under 25 U.S.C. 102(b) as being anticipated by Collins et al. (US 5,700,804).

Collins et al. disclose the diketopiperazines of formula I of the instant application, that have utility as inhibitors of PAI (plasminogen activator inhibitor) and can be used in the treatment of haemostatic disorders (column 13, lines 35-44, claim 1 of instant application). Collins et al. disclose pharmaceutical compounds of formula I of the instant application wherein R¹ and R² is a hydrogen and R³, R⁴, R⁵, and R⁶ is a hydrogen or an aryl radical that is an optionally substituted phenyl with the proviso that at least one radical be aryl (see abstract, claims 1,2, and 14-16 of instant application). Additionally, Collins et al. teach the compound of formula I formulated for use as a pharmaceutical composition comprising a pharmaceutically acceptable carrier such as lactose, dextrose, or cellulose which are commonly used in solid oral formulations (see column 15, lines 7-48, claims 1-5 and 7-11 of instant application). The method of stabilizing a cosmetic or pharmaceutical formulation will be practiced once the

photostable UV-A filter (diketopiperazine of formula I) is contacted with additives (such as lactose, dextrose, or cellulose) suitable for cosmetic or pharmaceutical formulations (claim 3 of instant application). The method of protecting skin or hair against solar rays will be practiced once a patient with haemostatic disorders uses a composition comprising the diketopiperazine of formula I (claim 1 of instant application).



Formula I

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 6-8, 12, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Collins et al. (US 5,700,804).

Applicant's Invention

Applicant claims a method for protecting hair or skin against solar rays (i.e., UV light in a range from 280-400 nm, claim 6 of instant application) comprising applying a composition comprising: a diketopiperazine of formula I wherein R¹ and R² may be a

hydrogen or a C₁-C₁₂-alkyl radical that is a branched alkyl chain or an unbranched alkyl chain and R³, R⁴, R⁵, and R⁶ may be a hydrogen, a C₁-C₁₂-alkyl radical that is a branched alkyl chain or an unbranched alkyl chain, or an aryl radical that is an optionally substituted phenyl, methoxy phenyl, cyanophenyl, or naphthyl radical, with the proviso that at least one radical be aryl; and optionally, one or more additional compounds known for cosmetic and pharmaceutical preparations.

***Determination of the scope and the content of the prior art
(MPEP 2141.01)***

The teachings of Collins et al. are incorporated herein by reference and are therefore applied in the instant rejection as discussed above.

***Ascertainment of the difference between the prior art and the claims
(MPEP 2141.02)***

Collins et al. do not teach a diketopiperazine of formula I wherein R¹ and R² may be a C₁-C₁₂-alkyl radical that is a branched alkyl chain or an unbranched alkyl chain and R³, R⁴, R⁵, and R⁶ may be a C₁-C₁₂-alkyl radical that is a branched alkyl chain or an unbranched alkyl chain. Also, Collins et al. do not teach a method for protecting hair or skin against solar rays of UV light in a range from 280-400 nm.

Finding of prima facie obviousness

Rationale and Motivation (MPEP 2142-2143)

In reference to claims 7,8,12 and 13, which deal with the use of a C₁-C₁₂-alkyl radical, it would be obvious to use an alkyl versus a hydrogen substituent, as done in the instant application, when attached to a carbon or nitrogen because this type of substitution would not affect the biological activity of the compound on the inhibition of the plasminogen activator inhibitor. See *In re Wood*, 199 USPQ 137 (CCPA 1978) ; *Ex parte Bluestone*, 135 USPQ 199 (Board of Patent Appeals and Interferences 1961).

In reference to claim 6, the method of protecting skin or hair against all solar rays will be practiced once a patient with haemostatic disorders uses a composition comprising the diketopiperazine of formula I.

Conclusion

No claims are allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR Only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

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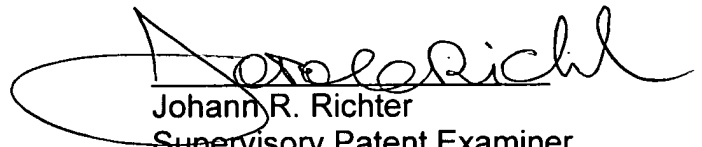
Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Courtney Brown, whose telephone number is 571-270-3284. The examiner can normally be reached on Monday-Friday from 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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